Applicant disagrees with this objection but notes that a typographical error in applicant's Response filed June 4, 1997 incorrectly referred to "page 15, lines 6-10" as supporting the recitation of specific levels of saturation. Support for "25-75% saturation of total IL-2 receptors" can be found on page 52, lines 6-10. Reconsideration and withdrawal is respectfully requested.

The Advisory Action also indicates objection to claim 1 in that the Examiner views "the ratio" as referring to a ratio of anti-Tac to radionuclide while the present claim refers to a ratio of conjugated to unconjugated anti-Tac. Support for the ratio used in claim 1 can be found in claim 1 as originally filed, which recites "wherein the therapeutic amount comprises 2-100 mg of anti-Tac wherein 5-15 mCi ^{90}Y conjugate is provided." This language makes clear that the "anti-Tac" refers to unconjugated Tac antibody and "^{90}Y conjugate" refers to ^{90}Y-conjugated Tac antibody. Radionuclide (i.e. ^{90}Y) is not a conjugate until it is bound to another molecule. Here, ^{90}Y is conjugated to a Tac antibody, thus forming a "^{90}Y-conjugate". Also, applicant respectfully directs the Examiner's attention page 42, lines 14-17 of the specification, wherein applicant describes mixing "labelled, unconjugated anti-Tac" with "radiolabelled anti-Tac" in preparing a dose for patient administration. Finally, the specification specifically identifies the "administered antibody" as the "sum of radiolabeled and unmodified antibody" (see page 17, lines 24-25). Hence, applicant submits that the specification supports the instant claims and makes clear that the present invention is focused on providing the proper ratio of unconjugated to conjugated ^{90}Y-anti-Tac. Reconsideration and withdrawal is respectfully requested.

Also in the Advisory Action, claim 1 is objected to under 35 U.S.C. §112 first and second paragraphs on the ground that determining the degree of saturation *in vivo* is not enabled. Applicant respectfully disagrees with this objection.

The determination of total IL-2R and the percent of saturation is well-known in the art and is set forth in the instant specification. In particular, soluble IL-2R is measured by assay of fresh serum from patients by ELISA, as described in the instant specification on page 44, line 2-4. This method is also described by Rubin *et al.* 1990 *Ann. Intern. Med.*, 113:619 (cited and incorporated by reference into the specification). Soluble IL-2R is directly proportional to total IL-2R levels in a patient. The degree of saturation of IL-2R is determined by use of two different antibodies recognizing IL-2R, each labelled for detection. One antibody is anti-Tac and the second, "7G7", recognizes a distinct epitope of IL-2R. By measuring the binding levels (by label detection) of each of these different IL-2R antibodies, the degree of IL-2R saturation can be readily measured. This technique is generally described in Example 14, beginning on page 46 of the instant specification. Hence, applicant submits that sufficient guidance is provided in the instant specification to enable determination of percent saturation of IL-2 receptors. Reconsideration and withdrawal is respectfully requested.

AUTHORIZATION

No additional fee is believed to be necessary.

The Commissioner is hereby authorized to charge any additional fees which may be required for this response, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2026-4003US3.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition and for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2026-4003US3.

A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

Dated: August 4, 1997

By: _____
Dorothy R. Auth
Reg. No. 36,434

MAILING ADDRESS:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, New York 10154
(212) 758-4800
(212) 751-6849 (Facsimile)